

What is claimed is:

1. An article ~~suitable for use in~~ for determining the presence or amount of analyte in a biological sample, said article comprising a multiple-layer element comprising:

(a) a base layer having two major surfaces, said base layer further having an opening, a flow channel, and an optical reading chamber, one end of which flow channel communicates with said opening in said base layer and the other end of which flow channel communicates with said optical reading chamber; and

(b) a cover layer in face-to-face contact with the major surface of said base layer containing said opening, said cover layer having an opening therein to vent said element.

2. The article of claim 1, wherein said optical reading chamber does not extend completely through said base layer.

3. The article of claim 1, wherein at least one reagent with which the analyte in the sample reacts to form an optically detectable reaction product is disposed in said optical reading chamber.

4. The article of claim 3, wherein said at least one reagent comprises hexokinase.

5. The article of claim 3, wherein said at least one reagent comprises glucose dehydrogenase.

6. The article of claim 3, wherein said at least one reagent comprises diaphorase.

7. The article of claim 1, wherein said second opening communicates with a vent channel.

8. The article of claim 1, wherein said optical reading chamber is cylindrical in shape.

9. The article of claim 1, wherein said optical reading chamber has a volume no greater than about 1 μ L.

10. The article of claim 1, wherein said cover layer has a portion capable of transmitting light in register with said optical reading chamber.

11. The article of claim 1, wherein said base layer has a portion capable of transmitting light in register with said optical reading chamber.

12. The article of claim 1, wherein said second opening is not directly over said optical reading chamber.

13. An article ~~suitable for use in~~ for determining the presence or amount of analyte in a biological sample, said article comprising a multiple-layer element comprising;

(a) a core layer having two major surfaces, said core layer further having an opening, a flow channel, and an optical reading chamber, one end of which flow channel communicates with said opening in said core layer and the other end of which flow channel communicates with said optical reading chamber; and
(b) a base layer in face-to-face contact with one major surface of said core layer; and
(c) a cover layer in face-to-face contact with the other major surface of said core layer, said cover layer having an opening therein to vent said element.

14. The article of claim 13, wherein said optical reading chamber extends completely through said core layer.

Subt A2 15. The article of claim 13, wherein at least one reagent with which said analyte in the sample reacts to form an optically detectable reaction product is disposed in said optical reading chamber.

- 16 15
16. The article of claim 15, wherein said at least one reagent comprises hexokinase.
- 17 15
17. The article of claim 15, wherein said at least one reagent comprises glucose dehydrogenase.
- 18 15
18. The article of claim 15, wherein said at least one reagent comprises diaphorase.
- 19 13
19. The article of claim 13, wherein said second opening communicates with a vent channel.
- 20 13
20. The article of claim 13, wherein said optical reading chamber is cylindrical in shape.
- 21 13
21. The article of claim 13, wherein said optical reading chamber has a volume no greater than about 1 μ L.
- 22 13
22. The article of claim 13, wherein said cover layer has a portion capable of transmitting light in register with said optical reading chamber is transparent.
- 23 13
23. The article of claim 13, wherein said base layer has a portion capable of transmitting light in register with said optical reading chamber.
- 24 13
24. The article of claim 13, wherein said second opening is not directly over said optical reading chamber.
- 25
25. A method for measuring the concentration of analyte in a sample comprising the steps of:
- (a) obtaining a sample of biological fluid from the body of a patient;
- (b) introducing the sample to the article of claim 1;
- (c) allowing at least one reagent in the article to react with the analyte of interest in the sample; and
- (d) measuring the concentration of analyte in the sample by optical instrument.

26 The method of claim 25, wherein the biological fluid is interstitial fluid.

27 The method claim 25, wherein said at least one reagent comprises
5 hexokinase.

28 The method claim 25, wherein said at least one reagent comprises
glucose dehydrogenase.

10 The method claim 25, wherein said at least one reagent comprises
diaphorase.

15 A method for measuring the concentration of analyte in a sample
comprising the steps of:

- (a) obtaining a sample of biological fluid from the body of a patient;
- (b) introducing the sample to the article of claim 13;
- (c) allowing at least one reagent in the article to react with the analyte of interest in the sample; and
- (d) measuring the concentration of analyte in the sample by optical instrument.

20 The method of claim 30, wherein the biological fluid is interstitial fluid.

25 The method claim 30, wherein said at least one reagent comprises
hexokinase.

30 The method claim 30, wherein said at least one reagent comprises
glucose dehydrogenase.

35 The method claim 30, wherein said at least one reagent comprises
diaphorase.